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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,236	02/09/2004	Craig A. Rosen	PS751P1	7334

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HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,236	ROSEN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 1-14 are pending in the application.

[3] In view of the numerous priority applications, applicant is requested to point out which – if any – application(s) disclose(s) the elected invention.

Election/Restrictions

[4] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to the use of a polypeptide for the preparation of a diagnostic or pharmaceutical composition, classified in class 514, subclass 2.

II. Claim 3, drawn to the use of an antibody for the preparation of a diagnostic or pharmaceutical composition, classified in class 424, subclass 139.1.

III. Claims 4-5, drawn to the use of a nucleic acid for the preparation of a diagnostic or pharmaceutical composition, classified in class 514, subclass 44.

IV. Claim 6, drawn to the use of an agonist for the preparation of a diagnostic or pharmaceutical composition, classified in class 514, subclass 789.

V. Claim 6, drawn to the use of an antagonist for the preparation of a diagnostic or pharmaceutical composition, classified in class 514, subclass 789.

VI. Claims 7-8, drawn to a polypeptide, classified in class 530, subclass 350.

VII. Claim 9, drawn to the use of a polypeptide for identifying a binding partner, classified in class 435, subclass 7.1.

VIII. Claim 10, drawn to an antibody, classified in class 530, subclass 387.9.

IX. Claims 11-14, drawn to a nucleic acid, a recombinant vector, and a recombinant host cell, classified in class 435, subclass 325.

[5] If applicant should elect the invention of Group I, II, IV, V, VI, VII, or VIII, restriction to a single polypeptide of SEQ ID NO:204 to 396 is also required under 35 U.S.C. 121. Thus, if applicant elects Group I, II, IV, V, VI, VII, or VIII, applicant is further required under 35 U.S.C. 121 to elect a single polypeptide of SEQ ID NO:204 to 396 for examination on the merits.

[6] If applicant should elect the invention of Group III or IX, restriction to a single nucleic acid encoding SEQ ID NO:11 to 203 is also required under 35 U.S.C. 121. Thus, if applicant elects Group III or IX, applicant is further required under 35 U.S.C. 121 to elect a single nucleic acid encoding SEQ ID NO:11-203 for examination on the merits.

[7] The inventions are distinct, each from the other because:

[8] SEQ ID NO:204 to 396 are related as being polypeptides. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as

claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the polypeptides of SEQ ID NO:204 to 396 are structurally distinct and no single polypeptide of SEQ ID NO:204 to 396 would render any of the others obvious to one of ordinary skill in the art and it follows that antibodies that bind to each of SEQ ID NO:204 to 396 are distinct and are not obvious variants.

[9] SEQ ID NO:11 to 203 are related as being nucleic acids. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the nucleic acids of SEQ ID NO:11 to 203 are structurally distinct and no single nucleic acid of SEQ ID NO:11 to 203 would render any of the others obvious to one of ordinary skill in the art.

[10] The polypeptide of group VI and polynucleotide of group IX are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, the information provided by the polynucleotide of group IX can be used to make a materially different polypeptide than that of group VI.

For example, a nucleic acid which hybridizes to SEQ ID NO:11, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO:204. In addition, while a polypeptide of group VI can made by methods using some, but not all, of the polynucleotides that fall within the scope of group IX, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. Also, the polypeptide can be made using purely synthetic means. For these reasons, the inventions of groups VI and IX are patentably distinct.

Furthermore, searching the inventions of groups VI and IX together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups VI and IX have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above;

furthermore, a search of the nucleic acid molecules of claim 11 would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group VI. As such, it would be burdensome to search the inventions of groups VI and IX together.

The polypeptide of group VI and the antibody of group VIII are patentably distinct for the following reasons: While the inventions of both group VI and group VIII are polypeptides, in this instance the polypeptide of group VI is a single chain molecule that functions as an enzyme, whereas the polypeptide of group VIII encompasses antibodies including IgG which comprises 2 heavy and light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group VI and the antibody of group VIII are structurally distinct molecules; any relationship between a polypeptide of group VI and an antibody of group VIII is dependent upon the correlation between the scope of the polypeptides that the antibody or binding partner binds and the scope of the antibodies or binding partners that would be generated using the polypeptide. In this case, the polypeptide of group VI is a large molecule which contains potentially hundreds of regions to which an antibody or binding partner may bind, whereas the antibody of group VIII is defined in terms of its binding specificity to a small structure within, *e.g.,* SEQ ID NO:204. Thus the polypeptide of group VI would result in the production of antibodies or binding partners outside the scope of group VIII. Furthermore, an antibody of group VIII would not specifically bind all of the polypeptides of group VI because the polypeptides of group VI encompass

mutants and variants. Therefore the polypeptide and antibody are patentably distinct. Furthermore, searching the inventions of groups VI and VIII together would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody each require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibody of group VIII. Furthermore, antibodies which bind to an epitope of a polypeptide of group VI may be known even if a polypeptide of group VI is novel. Similarly, an amino acid sequence search for fragments of the polypeptide is required to determine the novelty and nonobvious of the antibodies of group VII, however such a search is not required or sufficient to identify all of the polypeptides of group VI. In addition, the technical literature search for the polypeptide of group VI and the antibody of group VII are not coextensive, e.g., antibodies or binding partners may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group IX and the antibody of group VIII are patentably distinct for the following reasons. The antibody of group VIII includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group VIII which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between

a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Binding partners, which encompasses small molecule organic compounds and other polypeptides, are structurally distinct molecules. In the present claims, a polynucleotide of group IX will not encode an antibody of group VIII and the antibody of group VIII cannot be encoded by a polynucleotide of group IX. Therefore the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of groups IX and VIII together would impose a serious search burden since a search of the polynucleotide of group IX would not be used to determine the patentability of an antibody of group VIII, and vice-versa.

[11] The polypeptide of Group VI and the methods of Groups I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group VI can be used as an antigen in the production of antibodies.

[12] The polypeptide of Group VI is unrelated to the methods of Groups II-V as it is neither used nor made by the methods of Groups II-V.

[13] The antibody of Group VIII is unrelated to the method(s) of Groups I, III-V, and VII as it is neither used nor made by the method(s) of Groups I, III-V, and VII.

[14] The antibody of Group VIII and the method of Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group VIII can be used as an affinity purification reagent for the polypeptide of Group VI.

[15] The polynucleotide of Group IX is unrelated to the method(s) of Groups I-II, IV-V, and VII as it is neither used nor made by the method(s) of Groups I-II, IV-V, and VII.

[16] The polynucleotide of Group IX and the method of Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group IX can be used for protein expression.

[17] Inventions (I-V) and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of group VII and the methods of groups (I-V) are unrelated as they comprise

distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for practicing the claimed methods differ significantly for each of the materials. Therefore, each method is divergent in materials and steps. For these reasons the Inventions VII and (I-V) are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of groups VII and (I-V) have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of groups VII and (I-V) together.

[18] The methods of groups I and VII are directed to the use of related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each of the methods of groups I and VII comprises different method steps and achieves different results.

[19] The methods of groups I-V are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the

instant case, each of the methods of groups I-V uses a different product and thus has a materially different design.

[20] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-IX are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature search requiring a different text and/or sequence search for each Group and thus, co-examination of the inventions of Groups I-IX would be a serious burden on the examiner.

[21] It is noted that claims 1-14 will be examined only to the extent the claims read on the elected subject matter.

[22] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[23] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

[24] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656